K061656

LASER
PAIN CLINICS

510(k) Summary
(per 21 CFR 807.92)

DEC 15 2006

I. Applicant

Laser Pain Clinics
300 N Highland, Suite 105
WNJ Medical Office Building
Sherman, Texas 75092

Contact Person: Holly Wright, Manager and President
LaserMD Management GP, LLC (General Partner)
c/o LaserMD Management GP, LLC
903.868.1350 telephone
206.203.2001 Facsimile
e-mail: holly.wright@laserpainclinics.com

Date Prepared: November 6, 2006

II. Device Name

Proprietary Name:	Laser-D68
Common/ Usual Name:	Infrared Lamp
Classification Name:	Lamp, infrared, therapeutic heating
Regulation Number:	890.5500
Product Codes:	ILY
Classification:	2
Classification Panel:	Physical Medicine

III. Predicate Device

Laser Pain Clinics is substantially equivalent to the Eltech s.r.l K-Laser (K050070) and the Advanced Medical Technologies Maestro MDTL Laser System (K053473). The devices are therapeutic medical lasers designed to deliver light energy to the target tissue.

IV. Intended Use of the Device

Laser-D68 System provides visible red and infrared therapy to provide topical heating for the temporary:

- Increase in local blood circulation
- Relief of minor muscles and joint aches, pains and stiffness
- Relaxation of muscles
- Relief of muscle spasms
- Relief of minor pain and stiffness associated with arthritis

V. Description of the Device

The Laser-D68 is a non-invasive, low energy infrared therapeutic medical laser that is intended to perform laser therapy in healthcare centers, physical therapy laboratories, and family doctor practices.

The Laser D68 is supplied with three different probes that are used to generate laser radiation when connected to the D68 driver unit. Probe #1 is a 660nm, Indium Gallium Aluminum Phoshpide (InGaAlP) laser diode (visible red light) with an adjustable treatment power output from 1 milliwatts (mW) to 50 milliwatts (mW) (in 1mW increments). Probe #2 is an 830nm, Gallium Aluminum Arsenide (GaAlAs) laser diode (infrared light) with an adjustable treatment power output from 20 milliwatts to 400 milliwatts (in 5mW increments). Probe #3 is a 904nm, Gallium Arsenide (GaAs) laser diode (infrared light) with adjustable treatment power output of either 5mW to 90mW (in 5mW increments) (45W laser power source) or 5 mW to 150mW (in 5 mW increment) (75W modulated laser power source).

Each of the laser probes are fully interchangeable with the D68 driver.

VI. Summary of the Technical Characteristics for the Laser-D68 to the referenced predicate devices.

The Laser-D68 and the aforementioned predicate devices are infrared lamps as defined in 21 CFR 890.5500. These devices use infrared diodes to emit invisible photonic energy to tissue. The intended use is identical for all devices.

VII. Testing

The testing of the Laser-D68 included electrical safety testing, laser safety testing and electromagnetic compatibility testing.

VIII. Safety & Effectiveness

There are no substantial differences between the Laser-D68 defined in this 510(k) submission and the predicate devices. They are similar to the technologies that are currently used in other similar medical devices.

The Laser-D68 included electrical safety testing, laser safety testing and electromagnetic compatibility testing.

The Laser-D68 meets the applicable requirements of CFR 1040.

The Laser-D68, as with the predicate devices, has been certified to the requirements of the Medical Devices Directive 93/42/EEC, and is CE Marked.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Laser Pain Clinics
% Ms. Holly Wright
Manager and President
300 N. Highland, Suite 105
Sherman, Texas 75092

DEC 15 2006

Re: K061656
Trade/Device Name: Laser D-68
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: November 6, 2006
Received: November 7, 2006

Dear Ms. Wright:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

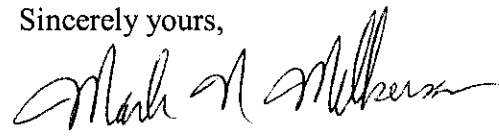
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

LASER
PAIN CLINICS

4. Indication for Use Statement

510(k) Number (if known): K061656

Device Name: Laser D-68

Indications for Use:

Laser-D68 System provides visible red and infrared therapy to provide topical heating for the temporary:

- Increase in local blood circulation
- Relief of minor muscles and joint aches, pains and stiffness
- Relaxation of muscles
- Relief of muscle spasms
- Relief of minor pain and stiffness associated with arthritis

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K061656 K061656 MNM